IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Art Unit: 1643
KOGANTY, et al.	)	Examiner: HOLLERAN, A.
Serial No.: 10/511,101	)	Washington, D.C.
Filed: September 12, 2005	)	February 13, 2008
For: SYNTHETIC GLYCO-LIPO-PEPTIDES AS VACCINES	)	Docket No.: KOGANTY=4A
	)	Confirmation No.: 6156

ELECTION WITH TRAVERSE

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S i r :

In response to the restriction requirement mailed January 14, 2008, Applicants respond as follows:

1. In response to the group-level restriction applicants elect group I with traverse. This is a partial traverse; group III claims have been cancelled.

The restriction between groups I and II is based on a holding of a posteriori lack of unity, i.e., that the glycolipopeptides of claim 1 are obvious over Karsten (1998) and Zheng (1996).

Karsten describes a series of synthetic 21-mer MUC1 derived glycopeptides which carry TF or Tn at different single or multiple positions, see Table 2. None of these glycopeptides are lipidated.

Zeng describes a synthetic lipopeptide, essentially a MAP-type branched peptide structure with a lipidated Lys, see compounds I-III. None of the lipopeptides are glycosylated.

Hence the issue is whether the art would have been motivated to lipidate Karsten's glycopeptides, or to glycosylate Zeng's lipopeptides.

The Examiner has not explained why, on the basis of the art relied on, the person of ordinary skill in the art would have been motivated to lipidate Karsten's MUC1 tandem repeat peptide or to glycosylate Zeng's lipidated influenza virus peptide.

However, that issue may become moot.

In EPO, the claims of applicants' counterpart rejection were rejected over a prior application with the same assignee, Jiang, PCT/US2000/031281 (November 15, 2000), published as WO 2001/03643 on May 24, 2001. There is a counterpart Jiang U.S. application, but since the PCT application is pre-AIPA (i.e., pre November 29, 2000), neither it nor the PCT application constitute 102(e) art against the instant application. The published PCT application is available here under 102(a)[1]. Jiang discloses glycolipopeptides BP1-219 and BP1-223, and thus is perhaps more relevant than the Karsten/Zeng combination presently relied on.

BP1-219 is identified in Fig. 35 as

H_2N-GVTSAPDT(Tn)RPAPGSTAS(Lipo) S(Lipo)L-OH

and BP1-223 as

H_2N-GVT(Tn)S(Tn)APDTRPAPGS(Tn)T(Tn) AS(Lipo)L-OH.

The European examiner has also relied on Price, et al., Tumor Biol. 19 (Suppl. 1):1-20 (1998) (made of record by IDS #2 on even date herewith).

Claim 1 has been amended on even date herewith to require that the glycolipopeptide comprises at least <u>two</u> MUC1 peptide epitopes, including <u>two</u> copies (which may be the same or different) of the MUC1 epitope defined by the formula P(D/E)(T/S)(R/K)P. (It may additionally comprise other epitopes, MUC1 or otherwise.) The glycopeptides of Karsten are 21-mers comprising a single instance of the 20-mer MUC1 tandem repeat and thus a <u>single</u> PDTRP.

With claim 1 so amended, both the art relied on by the USPTO and that relied on by EPO are distinguished, and hence the dependent method claims should be rejoined.

2. In response to the species restriction applicants elect glycolipopeptides comprising at least one MUC1-associated epitope, with traverse. Note that the claim as amended in fact

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[1] And is made of record by the January 31, 2008 IDS.

requires at least two such epitopes.

Applicants' concern is largely with interpretation of the species restriction. For example, if they elect "MUC1 epitope", must all the epitopes of the claimed lipoglycopeptide be MUC1 associated, or is it sufficient that at least one is (or, as claimed, that two are)?

Given that the examiner referred to claim 5, --which recites "at least one epitope is a MUC1 epitope"-- we assume that the latter interpretation is correct. We would like to have this confirmed, since, as the Examiner can see from Figs. 1 and 2, our lead molecules also comprise Tn and STn epitopes, which are cancer-associated (cp. claim 2) but not MUC1-associated. And claim 21 recites TF, another cancer-associated epitope.

If the Examiner intends to restrict us to glycolipopeptides in which all of the epitopes are MUC1-associated, we traverse, as the art does not disclose or suggest the subject matter presently claimed (see amendment filed on even date herewith). Since amended claim 1 distinguishes the art, without requiring that all epitopes be MUC1 peptide epitopes, it follows that applicants should not be limited to such a species.

To ensure that applicants can defend this interpretation, the species restriction is traversed.

Also, please note that we consider the term "MUC1 epitope" to include disclosed mutants, such as those within the scope of the claimed P(D/E)(A/G/T/S)(R/K/H)P formula. Again, our traversal preserves rights if the Examiner disagrees.

Respectfully submitted,

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